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09/827,371	04/06/2001	David Hung	05284.00085	3897

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/827,371	Hung
Examiner	**Art Unit**
Michele Flood	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 9, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1 and 6-33* is/are pending in the application.

4a) Of the above, claim(s) *12-33* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 6-11* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *10*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 9, 2002. Acknowledgment is made of Applicant's cancellation of Claims 2-5, and newly submitted Claims 16-33.

Election/Restriction

Newly submitted claims 16-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention of amended Claims 1 and 6-11 is drawn to a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast wherein the agent is selected from the Markush group recited in Claim 1, whereas the invention of newly submitted Claims 16-33 are drawn to a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast wherein the agent is selected from the Markush group recited in Claim 16; and, accessing the breast duct with a device and withdrawing a portion of the increased retrievable ductal fluid into the device. Thus, the newly submitted claims require an additional process step not required in the originally elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1 and 6-11 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6-11 as amended are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed September 9, 2002, now recite a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable

secreted ductal fluid from a breast wherein the agent is selected from the Markush group recited in Claim 1. However, the specification as originally filed provides only for a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast wherein the agent is selected from the Markush group recited in Claim 1.

Insertion of the above mentioned claim limitations have no support in the as-filed specification. The insertion of the limitations is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable **secreted ductal** fluid from a breast wherein the agent is selected from the Markush group recited in Claim 1. There is only one exemplified method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising the administration of an agent, namely mannitol, that increases the secretion of retrievable fluid in one or more breast ducts of the patient. For example, on page 3, lines 7-13 of the instant specification, Applicant discloses, "The invention is directed to ducts that are not filling and discharging, i.e., ducts that are not spontaneously discharging fluid or material, can be filled intraductally or otherwise treated, *e.g.*, systemically or locally to increase the retrievable fluid in a breast duct . . ."; and, the

instant specification specifically discloses on page 5, lines 5-24 that the instantly claimed method is directed to "[s]uccessful intraductal retrieval of ductal fluid from a non-spontaneously discharging duct" versus intraductal retrieval of fluid of **secreted ductal** fluid from a breast duct. Furthermore, Applicant specifically discloses on page 9, lines 13-17 of the instant specification: "Thus the intraductally administered agent can comprise, . . . e.g., . . . and an agent that increases fluid secretion from a breast duct epithelium." Nowhere does Applicant disclose the intraductal administration of an agent that increases **secreted ductal** fluid from a breast duct. As amended, the recitation of newly amended Claim 1 makes it appear that the claimed method is drawn to a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient wherein the ductal fluid is already secreted since the agent that is administered "increases retrievable secreted ductal fluid from a breast" vs. a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally an agent that increases the secretion of ductal fluid from a breast duct, as demonstrated by Applicant on page 14, lines 23-25: "The objective of these experiments was to test the effects of the introduction of a solution containing mannitol on the secretion of fluid from the breast ducts of live rabbits." This is not sufficient support for the new genus "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitations is considered to be the insertion of new matter for the above reasons.

As the above mentioned claim limitation could not be found in the present specification and despite Applicant pointing to page 5, lines 27-28 of the specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

This is a new matter rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 8-11 as amended remain rejected under 35 U.S.C. 102(e) as being anticipated by Love (A). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant's arguments have been fully considered but they are not persuasive for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast wherein the agent is selected from the Markush group recited in Claim 1.

Applicant argues that Love does not administer any of the agents as recited in claim 1. However, Applicant's argument is not persuasive because Love teaches a method for preparing for intraductal retrievable of fluid of fluid, cells and/or other material from a breast duct of a patient comprising the intraductal administration of a washing to a milk duct in the breasts of female human patients to retrieve fluids, marker substances, and cellular materials (see abstract). In Column 5, lines 61-64, Love teaches physiologic saline as a preferred washing fluid, "but contrast media and other physiologically sterile fluids may also be used." In Column 6, lines 55-67, Love discloses that "The volume of fluid introduced into the ductal network D_2 will be sufficiently large so that substantially the entire volume of the ductal network may be filled with

the washing fluid and excess fluid will flow from the network as it is displaced by additional fluid input . . . The remaining fluid will continue to be introduced and will thus flush the cellular and other marker materials from the ductal network into the opening . . ." After collection of the washing fluid comprising the retrievable fluid obtained from the breast duct through a double lumen catheter, Love teaches analyzing the fluid to identify a marker of a breast condition (see Column 5, lines 38-44). As Love expressly teaches the intraductal administration of physiologic saline to a breast duct for the retrieval of fluid, cells and/or other material from a breast of a patient, which is being read as "a hypotonic solution, a solution having a pH range of human tissue, a buffered solution, or a nonabsorbable biocompatible solution" as instantly claimed in the Markush group of Claim 1, and as disclosed on page 3, lines 21-26 of the instant specification, Love indeed teaches the administration of the same agent as instantly claimed by Applicant.

Love teaches a method for preparing for intraductal retrievable of fluid of fluid, cells and/or other material from a breast duct of a patient comprising the intraductal administration of a washing to a milk duct in the breasts of female human patients to retrieve fluids, marker substances, and cellular comprising intraductally administering physiologic saline to the breast of a patient. Love does not expressly teach that the referenced process for the intraductal administration of physiological saline results in increasing retrievable secreted fluid from a breast duct, however, the method taught by Love is a one-step process comprising the administration of the same ingredient, instantly claimed by Applicant. Thus, the claimed functional effect is

inherent to the method taught by Love because the ingredients, the materials to be treated, and the process steps are one and the same as disclosed in the invention claimed by Applicant.

Therefore, the cited reference is deemed to anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 6 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ogata et al. (B). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

Applicant argues that Ogata does not teach or suggest administering any of the instantly claimed ingredients of claim 1 into the teat of the cow. Applicant further argues that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to administer one of the recited agents that increases retrievable secreted ductal fluid from a breast duct in view of the disclosure of Ogata which does not teach or suggest administering any agents that increase retrievable secreted ductal fluid in a breast but rather teaches treating mastitis.

However, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed invention because Ogata teaches a method of injecting pressurized ozone into the teat orifice of a cow's (i.e, a patient's) breast via an ozone generator. In Column 3, lines 52-64, Ogata teaches that injecting pressurized ozone into the breast significantly expands the extremely narrow and elongated milk vessels located at deep regions, which thereby promotes discharge [of fluid] to the outside of the body. As Ogata teaches that ozone expands the milk ducts of the cow teat, the ozone taught by Ogata is being read as "a ductal orifice dilator"; and, thus Ogata indeed teaches one of the instantly claimed agents recited in claim 1.

The teachings of Ogata are set forth above. Although Ogata does teach administering ozone through the teat orifice of a cow (i.e., a patient) into the interior of the breast (see Column 1, lines 66-67 to Column 2, lines 1-4), Ogata does not expressly teach a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering to the patient an agent that increases secreted retrievable fluid from a breast duct, wherein the agent is intraductally administered. Although the "teat orifice"may not expressly constitute a breast duct *per se*, it would have been obvious to one of ordinary skill in the art at the time the invention was made to intraductally administer to the breast of a patient (i.e., a cow) the ozone taught by Ogata because Ogata teaches that ozone expands the milk vessels (also known as milk ducts) located at deep regions within the breast and promotes discharge. Thus, with Ogata providing the motivation and the suggestion to inject into the breast pressurized ozone to dilate or expand the narrow and elongated milk vessels located at deep regions within the breast, and

with Ogata clearly teaching that such administration of a ductal orifice dilator promotes the discharge of fluid (e.g., "inflaming products and infected milk") residing at deep regions of the breast, it would have been obvious to one of ordinary skill in the art at the time the invention was made to intraductally administer to the breast of a patient (e.g., a cow) the ozone taught by Ogata to provide the claimed method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast of a patient comprising administering intraductally an agent that increases retrievable secreted ductal fluid from a breast because Ogata teaches that injecting ozone into the breast provides the claimed functional effect of dilating breast ducts and increases retrievable secreted ductal fluid from a breast duct to the outside of the body. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to intraductally administer the ozone taught by Ogata to the breast of a patient (i.e., a cow) in a method of preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient to provide the claimed functional effect of increasing retrievable secreted fluid because Ogata teaches that ozone kills disease-causing microbes, supplies oxygen to the breast tissue, is cost-effective, and can be applied to a treatment for a dried up or blinded teat (see Column 3, lines 52 to Column 4, lines 1-58; and, Column 7, lines 7-11), and promotes discharge of fluid located deep within the vessels of breasts. Therefore, the invention as a whole was clearly prima facie obvious in the absence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6-11 as amended are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 157-165 of

copending Application No. 09/907,581. Newly applied as necessitated by amendment. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps, the actual ingredients, the subjects to which the ingredients are administered, and the claimed functional effect appear to be identical or essentially the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

November 8, 2002

CHRISTOPHER R. TATE
PRIMARY EXAMINER